I. REMARKS

Claims 1, 7, 22 and 85-99 are pending and are under examination.

A. Regarding enablement

Claims 1, 7, 22 and 8-99 are rejected as allegedly not enabled by the specification. Applicants respectfully traverse the rejection.

1. The allegations made in the Office Action:

In asserting this rejection, the Office Action makes the following allegations:

a. Alopecia is a multigenetic disorder (page 6 of the Office Action).

b. Alopecia is caused by both genetic and environmental factors (page 6 of the Office Action).

c. The specification is silent as to which alleles are associated with alopecia areata and alopecia of different etiology (page 6 of the Office Action).

d. It is unpredictable whether any polymorphism, including the specifically claimed polymorphic positions, would be associated with hair loss in different gender across different ethnicity of human population and genus of other species (page 8 of Office Action).

e. There is no evidence that loss of hair in this specific (HJMD) population measures with 95% confidence intervals across the (general hair loss) population (page 9 of the Office Action).

2. Response to these allegations:

Even if true, Applicants respectively submit that none of these allegations are relevant with respect to the central issue at hand – whether the invention as claimed can be practiced by the skilled artisan without undue experimentation.

Claim 1, as currently amended, recites as follows: A method of identifying a hair growth inducer comprising: identifying a molecule that induces P-cadherin; and testing whether said molecule is functional as a hair growth inducer. The skilled artisan would know how to perform the steps required by the claims as written, without undue experimentation, regardless of whether any or even all of the Action's allegations have merit.

For example, as disclosed on page 16 of the specification, "There are numerous [ways] for testing P-Cadherin function. Several assays are known for monitoring P-cadherin function, such as binding β-catenin and/or other cellular skeleton components. These assays include immunoprecipitation of cell extracts with an anti-Pcadherin antibody and immunoblotting of this reaction products to reveal a 116kD band representing P-cadherin as well as three smaller bands corresponding in decreasing size order to α-, β-, γ-catenins; microscopic examination of cell cultures in the presence of anti-E cadherin in which further inhibition of P-cadherin function leads to cell-cell interaction disruption and inhibition of keratinocyte differentiation; inhibition of actin cytoskeleton formation under changing Ca^{++} concentrations in keratinocyte cell-cultures (Lewis, J.E., Jensen, P.J. & Wheelock, M.J *J. Invest. Dermatol.* **102**, 870-877 (1994)). Furthermore, assessing an increase or decrease of P-Cadherin expression is taught in the specification and is well known in the art.

Thus, if a given candidate molecule increases or decreases P-Cadherin function or expression, this change in function or expression can be measured, for example, by the specific ways outlined above. Such a candidate molecule can then be tested, for example, on a subject to see if it induces hair growth. Either it will or will not induce hari growth, regardless of the subject being tested. **This is all that claim 1 requires.**

In view of this, the allegations made by the current Office Action have no bearing on whether the skilled artisan can practice the invention as claimed:

a. Alopecia is a multigenetic disorder (page 6 of the Office Action).

Whether true or not, the skilled artisan can test a candidate molecule to see if it induces P-cadherin and then test it to see if it induces hair growth. Either it will work (to induce hair growth) or it will not. Either way, the skilled artisan would know how to practice the invention as claimed:

b. Alopecia is caused by both genetic and environmental factors (page 6 of the Office Action).

Same answer as above.

c. The specification is silent as to which alleles are associated with alopecia areata and alopecia of different etiology (page 6 of the Office Action).

Same answer as above.

d. It is unpredictable whether any polymorphism, including the specifically claimed polymorphic positions, would be associated with hair loss in different gender across different ethnicity of human population and genus of other species (page 8 of Office Action).

Same answer as above.

e. There is no evidence that loss of hair in this specific (HJMD) population measures with 95% confidence intervals across the (general hair loss) population (page 9 of the Office Action).

Same answer as above. Moreover, having a candidate molecule tested, for example, on a subject having HJMD is more than adequate to practice the claimed invention. There is no requirement in the claim that it be tested in all sectors of the hair loss population.

The same arguments made above apply to independent claim 17 and all claims dependent on either claim 1 or 17.

Thus, in view of the nature of these claims as written, Applicants respectfully request that this rejection be withdrawn.

B. Regarding anticipation

Claims 17, 22, 92, 94, 97 and 99 are rejected as allegedly anticipated by Sprecher et al. (Nature Genetics, 29:134-136 (2001)). Applicants respectfully traverse the rejection.

The Action alleges that Sprecher et al. teaches a P-cadherin or E-cadherin antibody being tested on the skin biopsies of an HJMD patient and a control subject (page 12 of Office Action).

In response, Applicants respectfully submit that this is not "testing whether said molecule is functional as a hair growth inhibitor," as required by claim 17 (and all claims dependent thereon). As made plain by Sprecher et al., the purpose of applying these antibodies to these biopsy samples was to assess the expression of P-cadherin, not to test its effect on hair growth. (See page 135, column 2 of Sprecher, and Fig. 2g).

More importantly, the skilled artisan would recognize that applying a candidate molecule to biopsy material is not a way to assess inhibition of hair growth, as required by claim 17. Simply put, biopsy material should not normally grow hair. So contacting such material with a P-cadherin inhibitor does not test whether such an inhibitor would also inhibit hair growth.

Accordingly, because Sprecher et al. does not teach all of the limitations of claim 17 (or any claim dependent thereon), Applicants respectfully request that this rejection be withdrawn.

II. CONCLUSION

All of the issues raised in the Office Action have been addressed and are believed to have been overcome. Accordingly, it is respectfully submitted that all the claims under examination in the subject Application are allowable. Therefore, Applicants respectfully request a Notice of Allowance to this effect.

Respectfully submitted,

Martin D. Moynihan

Martin D. Moynihan,
Registration Number 40,338

Date: November 24, 2008

Enclosure:

- Petition for Extension of Time (One Month)